

0960 5 OCT 28 P2:14

OCT 19 2005

September 23, 2005

Office of Special Nutritionals
Center for Food and Safety and Applied Nutrition
US Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Statements of Nutritional Support

Dear Sir or Madam:

Consider the following as notification of Statements of Nutritional Support as required under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act as Amended (21 USC 343(r)(6)) and in accordance with 21 CFR 101.93.

Distributor: Natreon, Inc.
14 A Jules Lane
P.O. Box 10837
New Brunswick, NJ 08906

Dietary ingredient: A specific extract of *Withania somnifera* as described in U.S. Patent Nos. 6,153,198 and 6,713,092.

Dietary supplement: A dietary supplement containing a specific extract of *Withania somnifera* as described in U.S. Patent Nos. 6,153,198 and 6,713,092.

Natreon, Inc. is a supplier of the raw material *Withania somnifera* extract protected under U.S. Patents 6,153,198 and 6,713,092 to marketers/manufacturers of dietary supplements.

Text of substantiated statements:


- Helps support blood sugar levels that are already within the normal range.
- Supports healthy cardiovascular function.
- Helps support cholesterol levels which are already within the normal range.
- Builds energy and reduces fatigue.
- Boosts energy and reduces fatigue.
- Helps restore and sustain energy levels.
- Energy Builder
- Boosts energy levels.
- Helps restore and balance energy levels.
- Helps promote more restful sleep.
- Helps promote better sleep.
- Reduces stress to help promote more restful sleep.

975 0162

LET 16813

- Reduces stress to help promote better sleep.

The information contained in this notice is complete and accurate. The distributor named above has substantiation that the statements are truthful and not misleading. If necessary, please address future correspondence to: Karen Weaver, Esq. Weaver Law Group, 549 Randolph Street, Suite 400, Chicago, IL 60661.



Venkat Raju
Natreon, Inc.